

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:4677
ANSWERED ON:18.04.2001
CLEARANCE OF DRUGS
RADHA MOHAN SINGH

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether number of complaints from drugs manufacturers against the drugs controller on account of delays in granting clearances for new drugs;
- (b) if so, the action is being taken to simplify and expedite the processing of new drug applications; and
- (c) the time by which the drugs controller stipulate and enforce for disposing off new drug applications?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) : No, Sir.

(b) : Efforts are being made to further streamline the process of clearing new drugs in terms of the relevant provisions of the Drugs and Cosmetics Rules as well as Schedule Y of the said Rules. A Panel of experts has been constituted to undertake in-depth evaluation of the data furnished by the applicants. A separate panel of experts has also been constituted for evaluating recombinant derived products.

(c) : Time frames have been laid down for approving the protocols and evaluating the results of the clinical trials during the different phases to expedite the process of clearing new drugs. Accordingly a period of 90 days will be available for clearing phase-I study while phase-II will be cleared within 45 days and phase -III within 60 days in consultation with the panel of experts.